Change Notification for the UK Blood and Tissue Services

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Implementation To be determined by each Service

CN 11-2026

Platelets in Additive Solution and Plasma for Neonatal Use, Leucocyte Depleted

	Content changed	Type of change	Guidelines affected
1	Annex 3: Provisional component specifications	New specification	Red Book

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1. Annex 3: Provisional component specifications

Guidelines affected	Reason for change
Red Book	This is a new provisional component specification to be added to Annex 3.

A3.13: Platelets in Additive Solution and Plasma for Neonatal Use, Leucocyte Depleted

An apheresis platelet component for neonatal use which contains less than 1×10^6 leucocytes per starting component and where the suspending medium comprises 30–50% plasma and 50–70% additive solution and anticoagulant.

A3.13.1: Technical information

- Chapter 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- The component may be prepared by splitting Platelets, Apheresis, in Additive Solution and Plasma, Leucocyte Depleted (see chapter A3.12) using a closed system.
- The component should contain $\geq40\times10^9$ platelets in a suitable ratio and volume of platelet additive solution and plasma to maintain the pH at ≥6.4 at the end of the shelf life of the component.
- The component may be leucodepleted as part of an apheresis process or by subsequent filtration of the platelet component.
- Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy. If platelets are to be issued as HPA-matched (e.g. HPA-1a or HPA-5b negative) then donors should be screened and found negative for all clinically significant HLA and HPA antibodies (as defined in chapter 16 and chapter 18). This screening can be done on an initial sample and does not need repeating at each donation unless the donor has been transfused or pregnant since the last antibody screen.
- A record which demonstrates that the donor has not been transfused since the initial negative screen for antibodies and, in the case of female donors, that the donor has not been pregnant since the initial negative screen for antibodies needs to be maintained.
- Platelets in Additive Solution and Plasma for Neonatal Use, LD should be administered through a CE/UKCA/UKNI marked transfusion set.

A3.13.2: Labelling

For general guidelines, see chapter 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Platelets in Additive Solution and Plasma for Neonatal Use, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number and, if divided, sub-batch number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*
- the name, composition and volume of the anticoagulant or additive solution

In addition, the following statements should be made:

"INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection"

A3.13.3: Storage

For general guidelines, see chapter 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets and on whether an open or closed system is used.

- Packs currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days but, due to concerns over bacterial contamination, would require either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen reduction procedure.

- If any production stage involves an open system, after preparation the component should be used as soon as possible. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours.

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided that no single interruption lasts for more than 8 hours and the total length of all interruptions is no longer than 24 hours.

A3.13.4: Testing

In addition to the mandatory and other tests required for blood donations described in chapter 9 and leucocyte counting (see chapter 6.3 and chapter 7.1.1), a minimum of 75% of those components tested for the parameters shown at Table A3.13 shall meet the specified values.

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

Table A3.13: Platelets in Additive Solution and Plasma for Neonatal Use, LD – additional tests

Parameter	Specification	Frequency of test
Volume (1)	Within locally defined range	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)
Platelet count (2)	≥40×10^9/unit	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)
pH at end of shelf life (3,4)	≥6.4	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)
Leucocyte count (5)	<1×10^6/starting component	As per chapter 6.3 and chapter 7.1.1

Notes on Table A3.13

1. Units measured and found to be <30 mL or >95 mL should only be issued for transfusion under concessionary release.
2. Units measured and found to have <40×10^9/unit, or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release.
3. If producing low numbers, use of most units is likely to make testing of outdated units impossible. In this situation, periodic checks to ensure end-of-shelf-life quality should be undertaken with the combination of blood pack platelet concentration and storage conditions in routine use.
4. A minimum of 95% of components tested shall meet the specified value.
5. Methods validated for counting low numbers of leucocytes must be used.

A3.13.5: Transportation

For general guidelines, see chapter 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation, the temperature of platelets must be kept as close as possible to the recommended storage temperature and on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.